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(71) Applicant: VIACOR, INC. [US/US]; 260-B Fordham Road, Wilmington, MA 01887 (US).

(72) Inventors: COHN, William, E.; 104 Lagrange Street, Chestnut Hill, MA 02467 (US). LIDDICOAT, John, R.; 68 Myrtle Street, Apt. 4, Boston, MA 02114 (US). WOOLFSON, Steven, B.; Constitution Marina, 28 Constitution Road, P.O. Box 51837, Boston, MA 02205 (US). STREETER, Richard, B.; 66 Brookside Avenue, Winchester, MA 01890 (US).

(74) Agent: PANDISCIO, Mark, J.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

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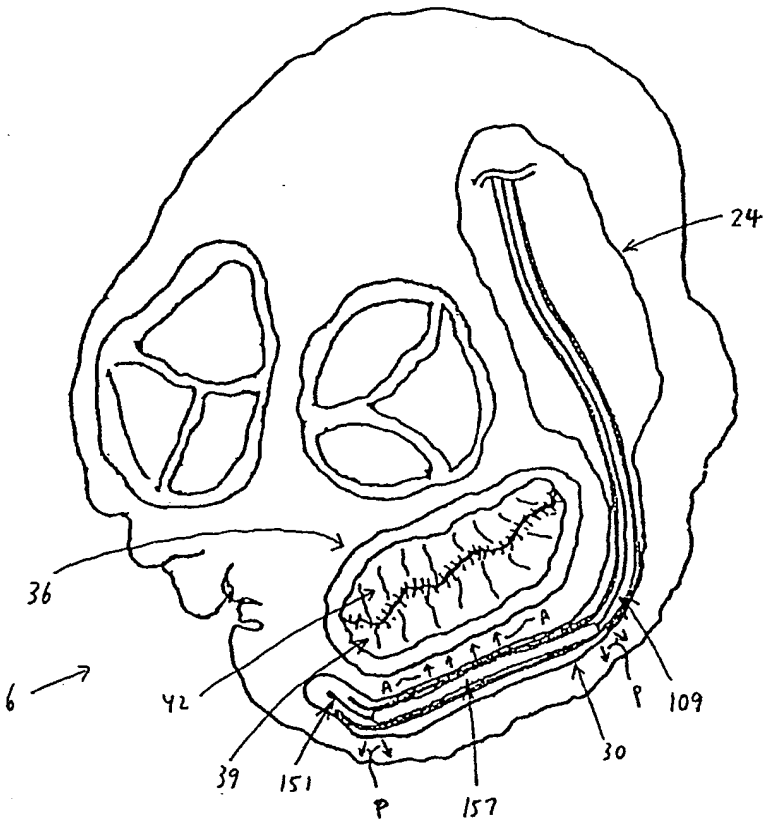

(57) Abstract: A method and apparatus for reducing mitral regurgitation. The apparatus is inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being configured to straighten the natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation and reduce mitral regurgitation.

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METHOD AND APPARATUS FOR IMPROVING MITRAL VALVE FUNCTION

CROSS-REFERENCE TO RELATED APPLICATION

This patent application:

(1) claims benefit of pending prior U.S. Patent Application Serial No. 60/391,790, filed 06/26/2002, by William E. Cohn et al. for METHOD AND APPARATUS FOR IMPROVING MITRAL VALVE FUNCTION (Attorney's Docket No. VIA-34 PROV); and

(2) is a continuation-in-part of pending prior U.S. Patent Application Serial No. 10/446,470, filed 05/27/2003, by Jonathan M. Rourke et al. for METHOD AND APPARATUS FOR IMPROVING MITRAL VALVE FUNCTION (Attorney's Docket No. VIA 43);

which are incorporated herein by reference.

Field Of The Invention

This invention relates to surgical methods and apparatus in general, and more particularly to surgical methods and apparatus for improving mitral valve function.

Background Of The Invention

Mitral valve repair is the procedure of choice to correct mitral regurgitation of all etiologies. With the use of current surgical techniques, between 70% and 95% of regurgitant mitral valves can be repaired. The advantages of mitral valve repair over mitral valve replacement are well documented. These include better preservation of cardiac function and reduced risk of anticoagulant-related hemorrhage, thromboembolism and endocarditis.

In current practice, mitral valve surgery requires an extremely invasive approach that includes a chest wall incision, cardiopulmonary bypass, cardiac and pulmonary arrest, and an incision on the heart itself to gain access to the mitral valve. Such a procedure is associated with high morbidity and mortality. Due to the risks associated with this procedure, many of the sickest patients are denied the potential benefits of surgical correction of mitral regurgitation. In addition, patients with moderate,

symptomatic mitral regurgitation are denied early intervention and undergo surgical correction only after the development of cardiac dysfunction.

Mitral regurgitation is a common occurrence in patients with heart failure and a source of important morbidity and mortality in these patients. Mitral regurgitation in patients with heart failure is caused by changes in the geometric configurations of the left ventricle, papillary muscles and mitral annulus. These geometric alterations result in incomplete coaptation of the mitral leaflets at systole. In this situation, mitral regurgitation is corrected by plicating the mitral valve annulus, either by sutures alone or by sutures in combination with a support ring, so as to reduce the circumference of the distended annulus and restore the original geometry of the mitral valve annulus.

More particularly, current surgical practice for mitral valve repair generally requires that the mitral valve annulus be reduced in radius by surgically opening the left atrium and then fixing sutures, or

more commonly sutures in combination with a support ring, to the internal surface of the annulus; this structure is used to cinch the annulus, in a pursestring-like fashion, to a smaller radius, thereby reducing mitral regurgitation by improving leaflet coaptation.

This method of mitral valve repair, generally termed "annuloplasty", effectively reduces mitral regurgitation in heart failure patients. This, in turn, reduces symptoms of heart failure, improves quality of life and increases longevity. Unfortunately, however, the invasive nature of mitral valve surgery and the attendant risks render most heart failure patients poor surgical candidates. Thus, a less invasive means to increase leaflet coaptation and thereby reduce mitral regurgitation in heart failure patients would make this therapy available to a much greater percentage of patients.

Mitral regurgitation also occurs in approximately 20% of patients suffering acute myocardial infarction. In addition, mitral regurgitation is the primary cause

of cardiogenic shock in approximately 10% of patients who develop severe hemodynamic instability in the setting of acute myocardial infarction. Patients with mitral regurgitation and cardiogenic shock have about a 50% hospital mortality. Elimination of mitral regurgitation in these patients would be of significant benefit. Unfortunately, however, patients with acute mitral regurgitation complicating acute myocardial infarction are particularly high-risk surgical candidates, and are therefore not good candidates for a traditional annuloplasty procedure. Thus, a minimally invasive means to effect a temporary reduction or elimination of mitral regurgitation in these critically ill patients would afford them the time to recover from the myocardial infarction or other acute life-threatening events and make them better candidates for medical, interventional or surgical therapy.

Summary Of The Invention

As a result, one object of the present invention is to provide an improved method and apparatus for reducing mitral regurgitation.

Another object of the present invention is to provide a method and apparatus for reducing mitral regurgitation which is minimally invasive.

Another object of the present invention is to provide a method and apparatus for reducing mitral regurgitation which can be deployed either permanently (e.g., for patients suffering from heart failure) or temporarily (e.g., for patients suffering from mitral regurgitation with acute myocardial infarction).

These and other objects are addressed by the present invention, which comprises an improved method and apparatus for reducing mitral regurgitation.

In one form of the invention, there is provided a method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to straighten the natural curvature of at least a portion

of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to move at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve anteriorly, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to reduce the degree of natural curvature of at least a

portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to increase the natural radius of curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus having a distal end, a

proximal end and an intermediate portion, the apparatus being configured so that when the apparatus is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends apply a posteriorly-directed force to the wall of the coronary sinus and the intermediate portion applies an anteriorly-directed force to the wall of the coronary sinus, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

inserting a substantially straight elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially straight elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially straight elongated body is positioned in

the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus and thereby improve leaflet coaptation.

In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

inserting a substantially rigid elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the substantially rigid elongated body being configured relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially rigid elongated body is positioned in the coronary sinus, it causes at least a portion of the coronary sinus to assume a different configuration adjacent to the posterior leaflet of the mitral valve, whereby to move

the posterior annulus anteriorly and thereby improve leaflet coaptation.

In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

inserting a straight, substantially rigid elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the straight, substantially rigid elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus and thereby improve leaflet coaptation.

In another form of the invention, there is provided an apparatus for reducing mitral regurgitation comprising:

a body having a distal end, a proximal end and an intermediate portion, the body being configured so that when the body is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends apply a posteriorly-directed force to the wall of the coronary sinus, and the intermediate portion applies an anteriorly-directed force to the wall of the coronary sinus, whereby to move the posterior annulus of the mitral valve anteriorly and thereby improve leaflet coaptation.

In another form of the invention, there is provided an apparatus for reducing mitral regurgitation comprising:

a substantially straight elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially straight

elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially straight elongated body is positioned in the coronary sinus, it causes at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus, moving it anteriorly, and thereby improve leaflet coaptation.

In another form of the invention, there is provided an apparatus for reducing mitral regurgitation comprising:

a substantially rigid elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially rigid elongated body is positioned in

the coronary sinus, it causes at least a portion of the coronary sinus to assume a different configuration adjacent to the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

In another form of the invention, there is provided an apparatus for reducing mitral regurgitation comprising:

a straight, substantially rigid elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the straight, substantially rigid elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of

curvature of the mitral annulus, moving it anteriorly, and thereby improve leaflet coaptation.

In accordance with a further feature of the present invention, there is provided a catheter comprising a flexible elongated delivery tube having a central lumen extending from a distal end of the tube to a proximal end of the tube, the flexibility of the tube being such as to permit closure of the distal end of the tube upon encounter with an impinging body structure, whereby to inhibit flow of fluid out of the distal end of the tube. Orifice means defined by the tube are disposed in a side wall thereof, the orifice means being disposed proximate but spaced from the distal end of the tube and configured to permit egress of fluid from the tube.

In accordance with a further feature of the invention, there is provided a catheter comprising a flexible elongated delivery tube having a central lumen extending from a distal end of the tube to a proximal end of the tube, and longitudinally extending surface grooves disposed in an outer surface of the

tube to permit flow of fluid longitudinally of the tube.

In accordance with a still further feature of the invention, there is provided an apparatus for reducing mitral regurgitation. The apparatus comprises a body having a distal end, a proximal end, and an intermediate portion, the body being configured such that when the body is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends apply a posteriorly-directed force to the wall of the coronary sinus, and the intermediate portion applies an anteriorly-directed force to the wall of the coronary sinus, whereby to move the posterior annulus of the mitral valve anteriorly and thereby improve leaflet coaptation. Longitudinally extending surface grooves are disposed in an outer surface of the body to permit flow of fluid longitudinally of the body.

Significantly, the present invention may be practiced in a minimally invasive manner, either

permanently or temporarily, so as to reduce mitral regurgitation.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:

Fig. 1 is a schematic view of portions of the human vascular system;

Fig. 2 is a schematic view of portions of the human heart;

Fig. 3 is a schematic view of a preferred system formed in accordance with the present invention;

Figs. 4-7 are a series of views illustrating use of the system of Fig. 3 to reduce mitral regurgitation;

Fig. 8 shows an alternative form of delivery catheter;

Fig. 9 shows an alternative form of flexible push rod;

Fig. 9A shows another alternative form of the present invention;

Figs. 10 and 11 show alternative constructions for the straight, substantially rigid elongated body;

Fig. 12 shows an alternative system formed in accordance with the present invention;

Fig. 13 shows use of the system shown in Fig. 12;

Fig. 14 is a schematic view of a known catheter shown being used in the introduction of a substantially straight, substantially rigid elongated body into place to reduce mitral regurgitation, and encountering a common problem;

Fig. 15 is a schematic view similar to Fig. 14 but illustrating an alternative catheter providing a solution to the aforesaid problem;

Fig. 16 is an enlarged sectional view of a portion of the catheter of Fig. 15;

Fig. 17 is a side elevational view of a further alternative catheter;

Fig. 18 is a sectional view taken along line XVIII-XVIII of Fig. 17;

Fig. 19 is a side elevational view of a still further alternative catheter; and

Fig. 20 is a sectional view taken along line XX-XX of Fig. 19.

Detailed Description Of The Preferred Embodiments

The coronary sinus is the largest vein in the human heart. During a large portion of its course in the atrioventricular groove, the coronary sinus typically extends adjacent to the left atrium of the heart for a distance of approximately 5 to 10 centimeters. Significantly, for a portion of its length, e.g., typically approximately 7-9 cm, the coronary sinus extends substantially adjacent to the posterior perimeter of the mitral annulus. The present invention takes advantage of this fact. More particularly, by deploying novel apparatus in the

coronary sinus, adjacent to the posterior leaflet of the mitral valve, the natural curvature of the coronary sinus may be modified in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly so as to improve leaflet coaptation and, as a result, reduce mitral regurgitation.

In one preferred embodiment of the invention, the novel apparatus comprises a straight, substantially rigid elongated body, the length of the straight, substantially rigid elongated body being sized so that when the straight, substantially rigid body is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the straight, substantially rigid elongated body will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

And in one preferred embodiment of the invention, access to the coronary sinus is gained percutaneously, e.g., the straight, substantially rigid elongated body is introduced into the patient's vascular system via the jugular vein or via the left subclavian vein, passed down the superior vena cava, passed through the right atrium and then passed into the coronary sinus, where it is deployed. Alternatively, the straight, substantially rigid elongated body may be introduced into the coronary sinus through a small incision in the heart, or through some other incision into the patient's vascular system.

And in one preferred embodiment of the invention, the straight, substantially rigid elongated body is guided into position by (i) passing it through a pre-positioned catheter, or (ii) passing it over a pre-positioned guidewire, or (iii) passing it guide-free (e.g., on the end of a steerable delivery tool) to the surgical site.

Once deployed, the novel apparatus may be left in position permanently (e.g., in the case of patients

suffering from mitral regurgitation associated with heart failure) or the novel apparatus may be left in position only temporarily (e.g., in the case of patients suffering from mitral regurgitation associated with acute myocardial infarction).

Visualization of the procedure may be obtained by fluoroscopy, echocardiography, intravascular ultrasound, angioscopy, real-time magnetic resonance imaging, etc. The efficacy of the procedure may be determined through echocardiography, although other imaging modalities may also be suitable.

Looking now at Fig. 1, there are shown aspects of the cardiovascular system 3 of a patient. More particularly, cardiovascular system 3 generally comprises the heart 6, the superior vena cava 9, the right subclavian vein 12, the left subclavian vein 15, the jugular vein 18, and the inferior vena cava 21. Superior vena cava 9 and inferior vena cava 21 communicate with the heart's right atrium 24. The coronary ostium 27 leads to coronary sinus 30. At the far end 31 (Fig. 2) of coronary sinus 30, the vascular

structure turns into the vertically-descending anterior interventricular vein ("AIV") 32 (see Fig. 1). For purposes of the present invention, it can generally be convenient to consider the term "coronary sinus" to mean the vascular structure extending between coronary ostium 27 and AIV 32.

As seen in Fig. 2, between coronary ostium 27 and AIV 32, coronary sinus 30 generally extends substantially adjacent to the posterior perimeter of the annulus 33 of the mitral valve 36. Mitral valve 36 comprises a posterior leaflet 39 and an anterior leaflet 42. In the case of a regurgitant mitral valve, posterior leaflet 39 and anterior leaflet 42 will generally fail to properly coapt at systole, thereby leaving an intervening gap 45 which will permit regurgitation.

Looking next at Fig. 3, there is shown a system 100 which comprises one preferred embodiment of the present invention. More particularly, system 100 generally comprises a guidewire 103, a delivery catheter 106 and a push rod 109.

Guidewire 103 comprises a flexible body 112 having a distal end 115 and a proximal end 118. The distal end 115 of guidewire 103 preferably includes a spring tip 121 for allowing the distal end of guidewire 106 to atraumatically traverse vascular structures, i.e., while the guidewire is being passed through the vascular system of a patient.

Delivery catheter 106 comprises a flexible body 124 having a distal end 127 and a proximal end 130, preferably with an adjustable valve 133 attached. A central lumen 136 extends from distal end 127 to proximal end 130. In some circumstances it may be desirable to provide a securing mechanism for securing the distal end of the delivery catheter within a vascular structure. By way of example but not limitation, a balloon 139 may be positioned about the exterior of flexible body 124, just proximal to distal end 127, with an inflation lumen 142 extending between balloon 139 and an inflation fitting 145.

Push rod 109 comprises a flexible body 148 having a distal end 151 and a proximal end 154. A straight,

substantially rigid elongated body 157, which may have a variety of different lengths, is formed on flexible body 148, proximal to distal end 151. A removable proximal stiffener or handle 160 may be placed between straight, substantially rigid elongated body 157 and proximal end 154.

System 100 may be used as follows to reduce mitral regurgitation.

First, distal end 115 of guidewire 103 is passed down the jugular vein 18 (or the left subclavian vein 15) of a patient, down superior vena cava 9, through right atrium 24 of the heart, and then into coronary sinus 30. See Fig. 4. It will be appreciated that as flexible guidewire 103 is passed down coronary sinus 30, the guidewire will tend to assume the natural curved shape of the coronary sinus, due to the flexible nature of the guidewire. The guidewire's atraumatic spring tip 121 will help ensure minimal damage to vascular structures as guidewire 103 is maneuvered into position.

Next, distal end 127 of delivery catheter 106 is placed over proximal end 118 of guidewire 103 and passed down the guidewire until the distal end of the delivery catheter is positioned in coronary sinus 30. See Fig. 5. Again, it will be appreciated that as the flexible delivery catheter 106 passes down the coronary sinus, the delivery catheter will tend to assume the natural curved shape of the coronary sinus, due to the flexible nature of the delivery catheter.

Once delivery catheter 106 has been positioned within the coronary sinus, guidewire 103 is removed. See Fig. 6. Either before or after guidewire 103 is removed, balloon 139 may be inflated so as to secure distal end 127 of delivery catheter 106 in position within coronary sinus 30.

Next, push rod 109 is passed down the central lumen 136 of delivery catheter 106. As the push rod's straight, substantially rigid elongated body 157 is passed down central lumen 136 of delivery catheter 106, it will force the delivery catheter to assume a straight configuration at the point where the

straight, substantially rigid elongated body 157 currently resides. As push rod 109 is pushed down delivery catheter 106, balloon 139 will hold the distal end of the delivery catheter in position within coronary sinus 30.

Push rod 109 is pushed down delivery catheter 106, utilizing removable proximal stiffener 160 as needed, until the straight, substantially rigid elongated body 157 is located adjacent to the posterior annulus of mitral valve 36. See Fig. 7. As this occurs, the presence of the straight, substantially rigid elongated body 157 in delivery catheter 106 will cause at least a portion of coronary sinus 30 to assume a substantially straight configuration at this point, so that the posterior annulus of mitral valve 36 is forced anteriorly. This will cause the mitral valve's posterior leaflet 39 to also move anteriorly so as to improve mitral valve leaflet coaptation and thereby reduce (or completely eliminate) mitral valve regurgitation. In this respect it should be appreciated that the posterior

annulus may be shifted anteriorly so as to achieve, or to attempt to achieve to the extent anatomically possible, leaflet-to-leaflet engagement or leaflet-to-annulus engagement (e.g., where a leaflet may be tethered due to left ventricular distortion). Both of these types of engagement, or targeted engagement, are intended to be encompassed by the terms "improved leaflet coaptation" and/or "increased leaflet coaptation" and the like. Using standard visualization means (e.g. echocardiography or fluoroscopy), the exact position of the straight, substantially rigid elongated body 157 is adjusted so as to reduce (or completely eliminate) regurgitation in mitral valve 36.

In this respect it should be appreciated that the straight, substantially rigid elongated body 157 is preferably sized to be somewhat less than the length of the coronary sinus between coronary ostium 27 and AIV 32. However, in some circumstances it may be desirable to size the straight, substantially rigid

elongated body 157 so that it will extend out of the coronary sinus and into the right atrium.

Furthermore, it should also be appreciated that the system provides a degree of tactile feedback to the user during deployment. More particularly, substantial resistance will typically be encountered as the straight, substantially rigid elongated body 157 is pushed out of right atrium 24 and into coronary sinus 30; then resistance will typically drop as body 157 is moved through the coronary sinus; and then resistance will typically increase significantly again as the distal tip of body 157 comes to the far end 31 of the coronary sinus. Thus, there is a sort of tactile "sweet spot" when the straight, substantially rigid elongated body 157 is located in the coronary sinus between coronary ostium 27 and AIV 32, and this tactile "sweet spot" can be helpful to the user in positioning the straight, substantially rigid elongated body 157 in coronary sinus 30.

At this point the straight, substantially rigid elongated body 157 is locked in position, e.g., by

closing an adjustable valve 133, and balloon 139 may be deflated.

System 100 is left in this position until it is no longer needed. In some cases this may mean that system 100 is left in position for a period of a few hours, days or weeks; in other cases system 100 may be substantially permanent. If and when system 100 is to be removed, push rod 109 is removed from delivery catheter 106, and then delivery catheter 106 is removed from the patient.

Thus it will be seen that with the present invention, the straight, substantially rigid elongated body 157 is essentially force-fit into the normally curved portion of the coronary sinus adjacent to the mitral valve's posterior leaflet. By properly sizing the length of the straight, substantially rigid elongated body 157 relative to the natural curvature of the patient's anatomy, and by properly positioning the straight, substantially rigid elongated body 157 in the patient's coronary sinus, the straight, substantially rigid elongated body will cause at least

a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve. This action will in turn drive the posterior annulus of the mitral valve anteriorly, so as to improve leaflet coaptation and thereby reduce mitral regurgitation. Thus, by inserting the straight, substantially rigid elongated body 157 into the coronary sinus adjacent to the posterior leaflet of the mitral valve, the annulus of the mitral valve is effectively manipulated so that it will assume an increased radius of curvature.

It has also been found that by inserting the straight, substantially rigid elongated body into the coronary sinus adjacent to the posterior leaflet of the mitral valve, the left ventricle may also be remodeled so as to help alleviate congestive heart failure.

It is significant to note that with the present invention, the distal and proximal ends of straight, substantially rigid elongated body 157 apply a posteriorly-directed force on the walls of coronary

sinus 30 (e.g., as shown with arrows P in Fig. 7) while the intermediate portion of straight, substantially rigid elongated body 157 applies an anteriorly-directed force on the walls of coronary sinus 30 (e.g., as shown with arrows A in Fig. 7).

In some cases the proximal end 130 of delivery catheter 106 may be fixed to the patient's outer skin using standard patient care methods such as adhesive tape, pursestring sutures, skin staples, etc. In other cases proximal end 130 of delivery catheter 106 may include a sewing cuff whereby the delivery catheter may be secured to the patient's tissue by suturing. See, for example, Fig. 8, where a sewing cuff 166 is shown attached to the proximal end 130 of delivery catheter 106. If desired, an element 169 may be provided proximal to adjustable valve 133, whereby flexible push rod 109 may be made fast to delivery catheter 106. By way of example, element 169 may comprise a crimpable element to secure flexible push rod 109 to delivery catheter 106, which is in turn secured to the patient. If desired, the proximal end

of the assembly may be embedded under the skin of the patient, e.g., in the case of a permanent implant.

As noted above, it can be helpful to anchor the distal end of delivery catheter 106 in position within the coronary sinus prior to pushing push rod 109 into the delivery catheter. Such an arrangement will keep the delivery catheter in place as the push rod makes the turn within the right atrium and enters the coronary sinus. In the absence of such anchoring, the push rod may drive the delivery catheter down the inferior vena cava 21. By securing the distal end of delivery catheter 106 to the walls of coronary sinus 30, the delivery catheter can be stabilized against diversion down the inferior vena cava 21 when the straight, substantially rigid elongate body 157 encounters initial resistance to making the turn into the coronary sinus.

The balloon 139 is one way of accomplishing such anchoring. However, it is also possible to utilize other types of securing mechanisms to anchor the distal end 127 of delivery catheter 106 in position

within coronary sinus 30, e.g., spring clips, ribs, etc.

Alternatively, and looking next at Fig. 9, the distal end 151 of push rod 109 may itself be provided with a distal anchor, e.g., such as the distal anchor 172 shown in Fig. 9.

It is also possible to prevent diversion of delivery catheter 106 down inferior vena cava 21 without anchoring the distal end of delivery catheter 106 or flexible push rod 109 to the walls of the coronary sinus. More particularly, and looking now at Fig. 9A, there is shown a support catheter 173 which is formed out of a more rigid material than delivery catheter 106. Support catheter 173 is constructed so that its distal end 174 can be positioned in coronary ostium 27 and then its sidewall 174A can support delivery catheter 106 adjacent to inferior vena cava 21 when push rod 109 is passed down delivery catheter 106, whereby to prevent delivery catheter 106 from diverting down inferior vena cava 106. Fig. 9A also

shows an introducer catheter 174B at the entrance to jugular vein 18.

As noted above, as push rod 109 is advanced to the region adjacent to the posterior annulus of the mitral valve, the straight, substantially rigid elongated body 157 will distort the natural configuration of the coronary sinus so that it will assume a substantially straight configuration. While this action induces the desired valve remodeling, it can also induce a significant stress on the walls of the coronary sinus, particularly at the distal and proximal ends of the straight, substantially rigid elongated body 157, where stress will be concentrated. To this end, the construction of the straight, substantially rigid elongated body 157 may be modified somewhat so as to better distribute this stress. More particularly, and looking next at Fig. 10, the distal and proximal ends of straight, substantially rigid elongated body 157 may include relatively flexible portions 175 to help better distribute the stress exerted on the walls of the coronary sinus.

Additionally, and/or alternatively, any taper applied to the distal and proximal ends of straight, substantially rigid elongated body 157 may be elongated, e.g., such as shown at 178 in Fig. 11, so as to better distribute the stress imposed on the walls of the coronary sinus.

Looking next at Fig. 12, there is shown a system 181 which comprises another preferred embodiment of the present invention. More particularly, system 181 generally comprises the guidewire 103, a straight, substantially rigid elongated body 184 and a push cannula 187.

Guidewire 103 is as previously described.

Straight, substantially rigid elongated body 184, which may have a variety of different lengths, comprises a distal end 188 and a proximal end 190. A central lumen 193 extends between distal end 188 and proximal end 190. Central lumen 193 accommodates guidewire 103.

Push cannula 187 comprises a distal end 194 and a proximal end 196. A central lumen 199 extends between

distal end 194 and proximal end 196. Central lumen 199 accommodates guidewire 103.

System 181 may be used as follows to reduce mitral regurgitation.

First, distal end 115 of guidewire 103 is passed down jugular vein 18 (or the left subclavian vein 15) of a patient, down superior vena cava 9, through right atrium 24 of the heart, and into coronary sinus 30. It will be appreciated that as flexible guidewire 103 is passed down coronary sinus 30, the guidewire will tend to assume the natural curved shape of the coronary sinus, due to the flexible nature of the guidewire. The guidewire's atraumatic spring tip 121 will help minimize damage to vascular structures as the guidewire is advanced into position.

Next, distal end 188 of straight, substantially rigid elongated body 184 is placed over proximal end 118 of guidewire 103 and passed a short distance down the guidewire. Then the distal end 194 of push cannula 187 is placed over proximal end 118 of guidewire 103, and then push cannula 187 is advanced

down the guidewire. As push cannula 187 is advanced down the guidewire, its distal end 194 pushes the straight, substantially rigid elongated body 184 ahead of it. See Fig. 13.

As the straight, substantially rigid elongated body 184 is passed down the coronary sinus, it will force the coronary sinus to assume a straight configuration at the point where the straight, substantially rigid elongated body 184 currently resides. Push cannula 187 is pushed down guidewire as needed, until the straight, substantially rigid elongated body 184 is located adjacent to the posterior annulus of the mitral valve. As this occurs, the presence of the straight, substantially rigid elongated body 184 in the coronary sinus will cause coronary sinus to assume a substantially straight configuration at this point, so that the posterior annulus of the mitral valve is forced anteriorly. This will cause the posterior mitral valve leaflet to also move anteriorly so as to improve leaflet coaptation and thereby reduce (or completely

eliminate) mitral valve regurgitation. Using standard visualization means (e.g. echocardiography or fluoroscopy), the exact position of the straight, substantially rigid elongated body may be adjusted so as to reduce (or completely eliminate) regurgitation in the mitral valve.

If desired, the push cannula 187 may be provided with a releasably attachable interface (e.g., a grasper) so that it may releasably secure the proximal end 190 of the straight, substantially rigid elongated body 184. Such a feature will permit the straight, substantially rigid elongated body to be pulled backward within the coronary sinus, either for positioning or removal purposes.

Alternatively, elongated body 184 or 157 may have any of a variety of non-straight shapes along its length. For example, the elongated body may be wavy, spiraled, or curved along all or a portion of its length. By way of example, elongated body 157 and/or 184 may have a curved configuration so as to invert the natural curvature of the coronary sinus, i.e., so

that it is bowed towards the anterior annulus. Or the elongated body may have a compound shape along its length, e.g., it may have a sort of "w" shape, with the center of the "w" being directed towards the anterior annulus. Any of these or other alternate shapes may effect the anterior displacement of the posterior annulus that results in reduction of the mitral valve regurgitation.

In other alternative embodiments, the elongated body may be flexible along at least a portion of its length. Regional flexibility and regional stiffness may allow for straightening of select locations of the coronary sinus and corresponding locations of the posterior mitral annulus. This can cause regions of the mitral annulus to move anteriorly, thus causing regional improvements in leaflet coaptation. In addition, the elongated body may be formed by two end segments connected together by a filament: by anchoring the two end segments relative to the anatomy and pulling the filament taught, the naturally curved wall of the coronary sinus can be straightened,

whereby to move the posterior mitral annulus anteriorly and thereby reduce mitral regurgitation.

In the preceding discussion, elongated body 157 (or 184) is generally described as being substantially straight and substantially rigid, with or without relatively flexible portions 175 (Fig. 10) and/or tapers 178 (Fig. 11). However, it should be appreciated that the terms "substantially straight", "substantially rigid", "relatively flexible", and the like, are meant to be interpreted in the context of the anatomical tissue involved and should not be interpreted in an absolute sense.

Fundamentally, elongated body 157 (or 184) is constructed so that (1) its intermediate portion imparts an anteriorly-directed force on the walls of the coronary sinus (e.g., as shown by the arrows A in Fig. 7), and (2) its distal and proximal ends impart a posteriorly-directed force on the walls of the coronary sinus (e.g., as shown by the arrows P in Fig. 7). Conversely, a high center load is imparted to the intermediate portion of elongated body 157 (or 184) by

the mitral annulus, and smaller end loads are directed to the distal and proximal ends of elongated body 157 (or 184) by the posterior portions of the coronary sinus.

Among other things, such an effect can be created by using an elongated body 157 (or 184) which is (1) straighter (but not necessarily perfectly straight) than the natural curvature of the portion of the coronary sinus adjacent to the posterior leaflet of the mitral annulus, and (2) more rigid (but not necessarily perfectly rigid) than the anatomical tissue which is to be displaced by the deployed elongated body 157 (or 184).

As noted above, in order to better distribute the loads on the proximal portions of the coronary sinus, the distal and proximal ends of elongated body 157 (or 184) may have relatively flexible portions 175 (Fig. 10) and/or tapers 178 (Fig. 11). Furthermore, the flexibility of these portions can vary along their length; thus, the elongated relatively flexible

tapered portions 178 (Fig. 11) can become more flexible as they extend toward their outer ends.

Indeed, there is nothing in the present invention which requires that the intermediate portion of elongated body 157 (or 184) be absolutely rigid; in fact, it will function satisfactorily so long as it is substantially resistive to the high center load imposed by the mitral annulus. The design is further enhanced by having the distal and proximal ends of elongated body 157 (or 184) be somewhat less resistive to the smaller end loads directed by the posterior walls of the coronary sinus. Thus, a satisfactory design may be implemented with a device which has a rigidity gradient along its length, with a highest rigidity at or near the center and lower rigidity at or near its two ends (or, conversely, a flexibility gradient along its length, with a lowest flexibility at or near the center and a higher flexibility at or near its two ends). This may be accomplished by tapering the elongated body; and/or by varying its composition and/or material properties; and/or by

other techniques which will be apparent to a person skilled in the art in view of the present disclosure. Or a satisfactory design may be implemented with a device which has some degree of flexibility along its entire length; and this flexibility may vary with length or it may be substantially constant along the entire length of the elongated body 157 (or 184).

Thus, as noted above, a satisfactory design may be implemented with an elongated body 157 (or 184) which is straighter (but not necessarily perfectly straight) than the natural curvature of the portion of the coronary sinus adjacent to the posterior leaflet of the mitral annulus, and (2) more rigid (but not necessarily perfectly rigid) than the anatomical tissue which is to be displaced by the deployed elongated body 157 (or 184).

In the system 100 described above, pushrod 109 (comprising the straight, substantially rigid elongated body 157) is delivered through delivery catheter 106. This construction can be advantageous inasmuch as the pushrod 109, and particularly its

elongated body 157, can be shielded from direct contact with the host vascular tissue as the pushrod is advanced into its working position within the coronary sinus. As a result, the pushrod can be moved into working position with less trauma to the host vascular tissue.

The interior of delivery catheter 106 is typically filled with fluid (e.g., blood) when the delivery catheter is positioned within the vascular system of the patient. When pushrod 109 is advanced down the interior of delivery catheter 106, this fluid is generally forced out the distal end of the delivery catheter, with pushrod 109 (and particularly elongated body 157) acting as something of a piston.

Unfortunately, in some situations the distal end of delivery catheter 106 may become partially or completely closed off. This may occur for a variety of reasons, e.g., the distal end of the catheter could be positioned in a narrowed-down region of the blood vessel (FIG. 14), or the distal end of the catheter could be orthogonally engaging the side wall of a

sharply-turning blood vessel, or the distal end of the catheter could be kinked over so as to close off the distal end of the catheter, or another, more-distal catheter-borne device could be blocking off the distal end of the catheter, etc.

In these and other situations, partial or complete closure of the distal end of the catheter can prevent fluid from escaping from the interior of the catheter. As a result, as pushrod 109 (and particularly elongated body 157) is advanced down the catheter, it meets the column of fluid and, inasmuch as the fluid is incompressible, encounters substantial resistance to advancement. This can render the device more difficult or even impossible for the operator to use. In addition, even where the operator can generate sufficient force to push the fluid out the distal end of the catheter, there is a danger that the fluid will be forced out with such pressure that it will damage the host tissue.

In view of the foregoing, it has been discovered that it can be advantageous to provide openings 200

(FIG. 15) in the side wall of delivery catheter 106. The openings 200 are preferably provided near to, but spaced from, the distal end 127 of the delivery catheter 106, although they may also be provided substantially anywhere along the length of the delivery catheter. The openings 200 permit fluid to escape from the interior of the delivery catheter 106 even when the distal end 127 of the delivery catheter is partially or completely blocked off, thus permitting easier passage of the pushrod 109 (and particularly elongated body 157) through a fluid filled catheter.

The aforementioned openings 200 may comprise holes 202, longitudinally-extending slits or slots, circumferentially-extending slits or slots 204, gills, and/or other aperture configurations so as to form the fenestrated catheter.

Referring to Fig. 16, it will be seen that the fenestrated catheter 106 may reside inside another catheter 173. The outer catheter 173 is dispsed around the fenestrated catheter 106 and spaced

therefrom to define a passageway 176 between the outer wall of the catheter 106 and the inner wall of the catheter 173. The passageway may be annular or, if the inner catheter is not centered in the outer catheter, may be of any configuration defined by the two catheters, so long as the openings 200 are in communication with the passageway. Preferably, the passageway extends to a proximal end of the outer tube.

It should also be appreciated that the undesirable "piston effect" described above can be ameliorated to some extent through other constructions. For example, in system 100 shown in Fig. 3, delivery catheter 106 may be provided with one or more longitudinally-extending surface grooves 206 (Figs. 17 and 18) so as to facilitate blood flow past the perimeter of delivery catheter 106.

Similarly, in system 181, shown in Fig. 12, elongated body 184 may be provided with one or more longitudinally-extending surface grooves 206 (Figs. 19

and 20) so as to facilitate blood flow past the perimeter of elongated body 184.

It is to be understood that the present invention is by no means limited to the particular constructions herein disclosed and/or shown in the drawings, but also comprises any modifications or equivalents within the scope of the claims.

What Is Claimed Is:

1. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being configured to straighten the natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

2. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being configured to move at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve

anteriorly, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

3. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being configured to reduce the degree of natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

4. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being configured to increase the natural radius of curvature of at least a portion of the coronary sinus in the vicinity of the

posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

5. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus having a distal end, a proximal end and an intermediate portion, the apparatus being configured so that when the apparatus is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends apply a posteriorly-directed force to the wall of the coronary sinus and the intermediate portion applies an anteriorly-directed force to the wall of the coronary sinus, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

6. A method for reducing mitral regurgitation comprising:

inserting a substantially straight elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially straight elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially straight elongated body is positioned in the coronary sinus, it causes at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus and thereby improve leaflet coaptation.

7. A method for reducing mitral regurgitation comprising:

inserting a substantially rigid elongated body into the coronary sinus of a patient in the vicinity

of the posterior leaflet of the mitral valve, the substantially rigid elongated body being configured relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially rigid elongated body is positioned in the coronary sinus, it causes at least a portion of the coronary sinus to assume a different configuration adjacent to the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

8. A method for reducing mitral regurgitation comprising:

inserting a substantially straight, substantially rigid elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior

leaflet of the mitral valve so that when the substantially straight, substantially rigid elongated body is positioned in the coronary sinus, it causes at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus and thereby improve leaflet coaptation.

9. An apparatus for reducing mitral regurgitation comprising:

a body having a distal end, a proximal end and an intermediate portion, the body being configured so that when the body is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends apply a posteriorly-directed force to the wall of the coronary sinus, and the intermediate portion applies an anteriorly-directed force to the wall of the coronary sinus, whereby to move the posterior annulus of the

mitral valve anteriorly and thereby improve leaflet coaptation.

10. An apparatus for reducing mitral regurgitation comprising:

a substantially straight elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially straight elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially straight elongated body is positioned in the coronary sinus, it causes at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus, moving the posterior annulus anteriorly, and thereby improve leaflet coaptation.

11. An apparatus for reducing mitral regurgitation comprising:

a substantially rigid elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially rigid elongated body is positioned in the coronary sinus, it causes at least a portion of the coronary sinus to assume a different configuration adjacent to the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

12. An apparatus for reducing mitral regurgitation comprising:

a substantially straight, substantially rigid elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the

posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially straight, substantially rigid elongated body is positioned in the coronary sinus, it causes at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus, moving the mitral annulus anteriorly, and thereby improve leaflet coaptation.

13. A catheter comprising:

a flexible elongated delivery tube having a central lumen extending from a distal end of said tube to a proximal end of said tube, the flexibility of said tube being such as to permit closure of the distal end of said tube upon encounter with an

impinging body structure, whereby to inhibit flow of fluid out the distal end of said tube; and

orifice means defined by said tube in a side wall thereof, said orifice means being disposed proximate but spaced from the distal end of said tube, and configured to permit egress of fluid from said tube.

14. The catheter in accordance with claim 13 wherein said orifice means comprises at least a selected one of holes, longitudinally-extending slits, longitudinally-extending slots, circumferentially-extending slits, circumferentially-extending slots, gills, and apertures of selected configurations.

15. The catheter in accordance with claim 14 and further comprising:

an outer flexible elongated tube disposed around said delivery tube and spaced therefrom to define a passageway between an outer wall of said delivery tube and an inner wall of said outer tube;

wherein the passageway is in communication with said orifice means.

16. The catheter in accordance with claim 15 wherein the passageway extends to a proximal end of said outer tube.

17. The catheter in accordance with claim 15 wherein the passageway is annular in widthwise configuration.

18. A catheter comprising:

a flexible elongated delivery tube having a central lumen extending from a distal end of said tube to a proximal end of said tube; and

longitudinally extending surface grooves disposed in an outer surface of said tube to permit flow of fluid longitudinally of said tube.

19. The catheter in accordance with claim 18 wherein said tube is provided with a second lumen extending alongside the central lumen.

20. An apparatus for reducing mitral regurgitation, the apparatus comprising:

a body having a distal end, a proximal end, and an intermediate portion, the body being configured such that when the body is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends apply a posteriorly-directed force to the wall of the coronary sinus, and the intermediate portion applies an anteriorly-directed force to the wall of the coronary sinus, whereby to move the posterior annulus of the mitral valve anteriorly and thereby improve leaflet coaption; and

longitudinally extending grooves disposed in an outer surface of said body to permit flow of fluid longitudinally of said body.

21. The apparatus in accordance with claim 20 wherein said body is provided with a central lumen extending from the distal end of said body to the proximal end of said body.

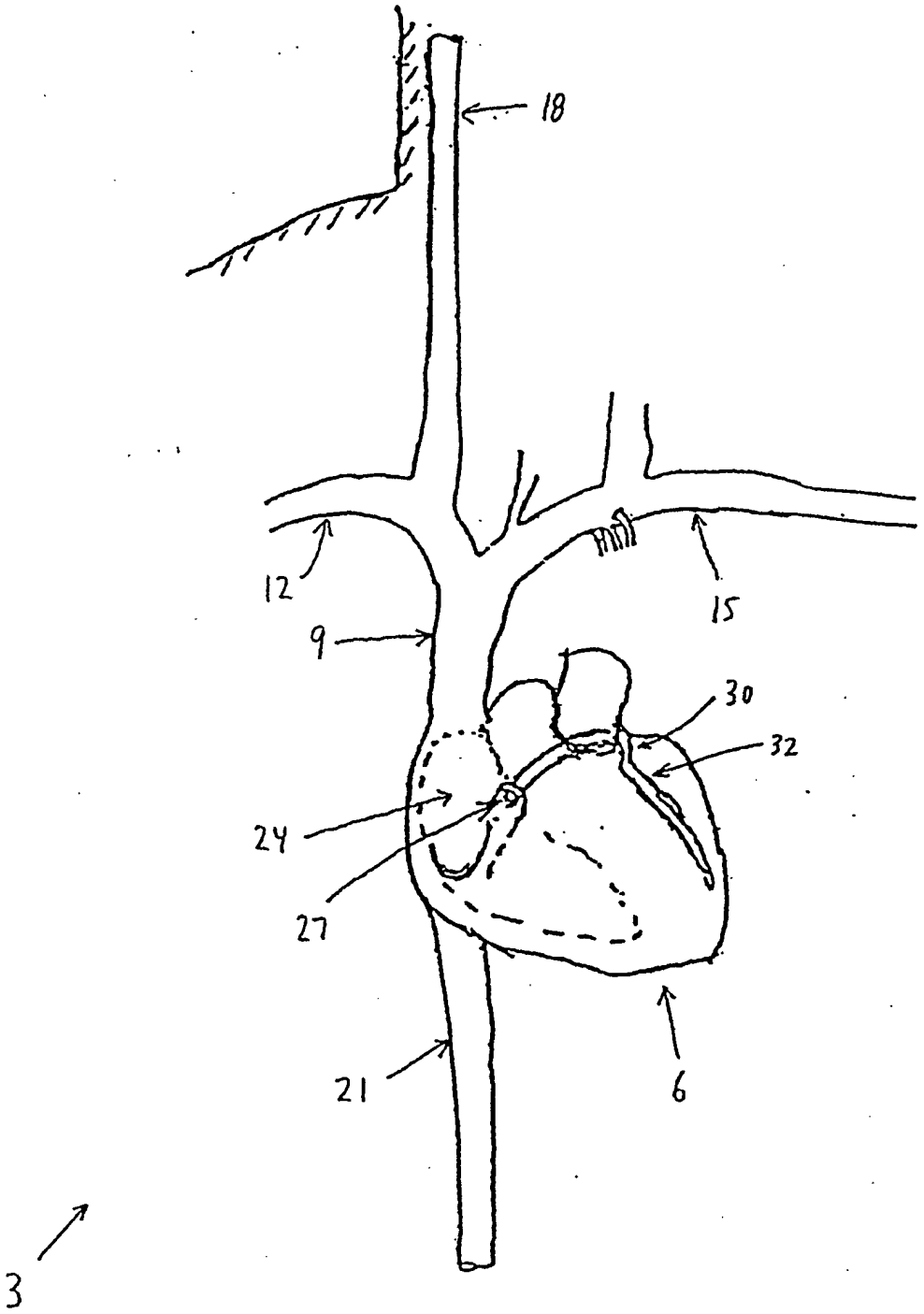

FIG. 1

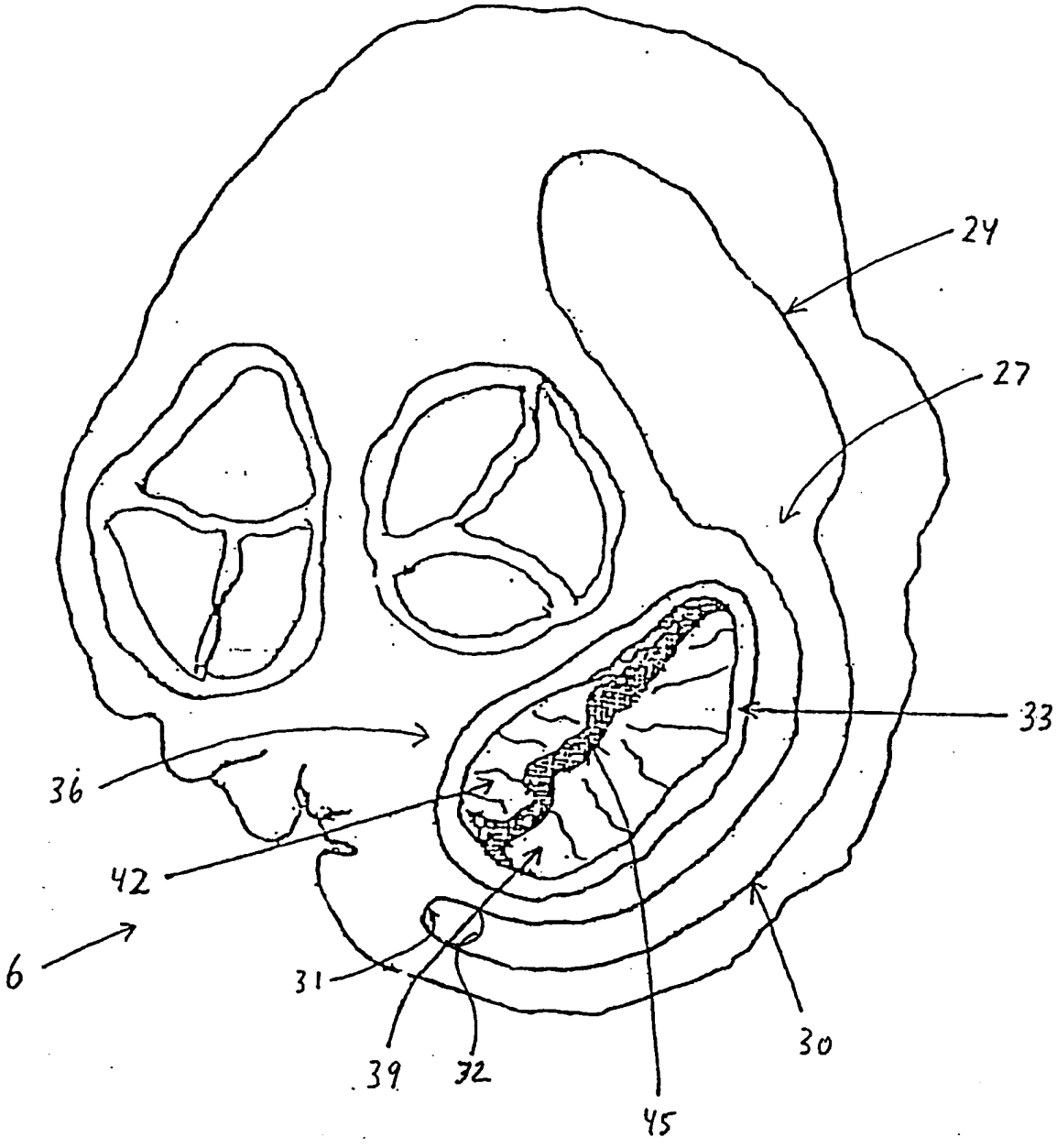

FIG. 2

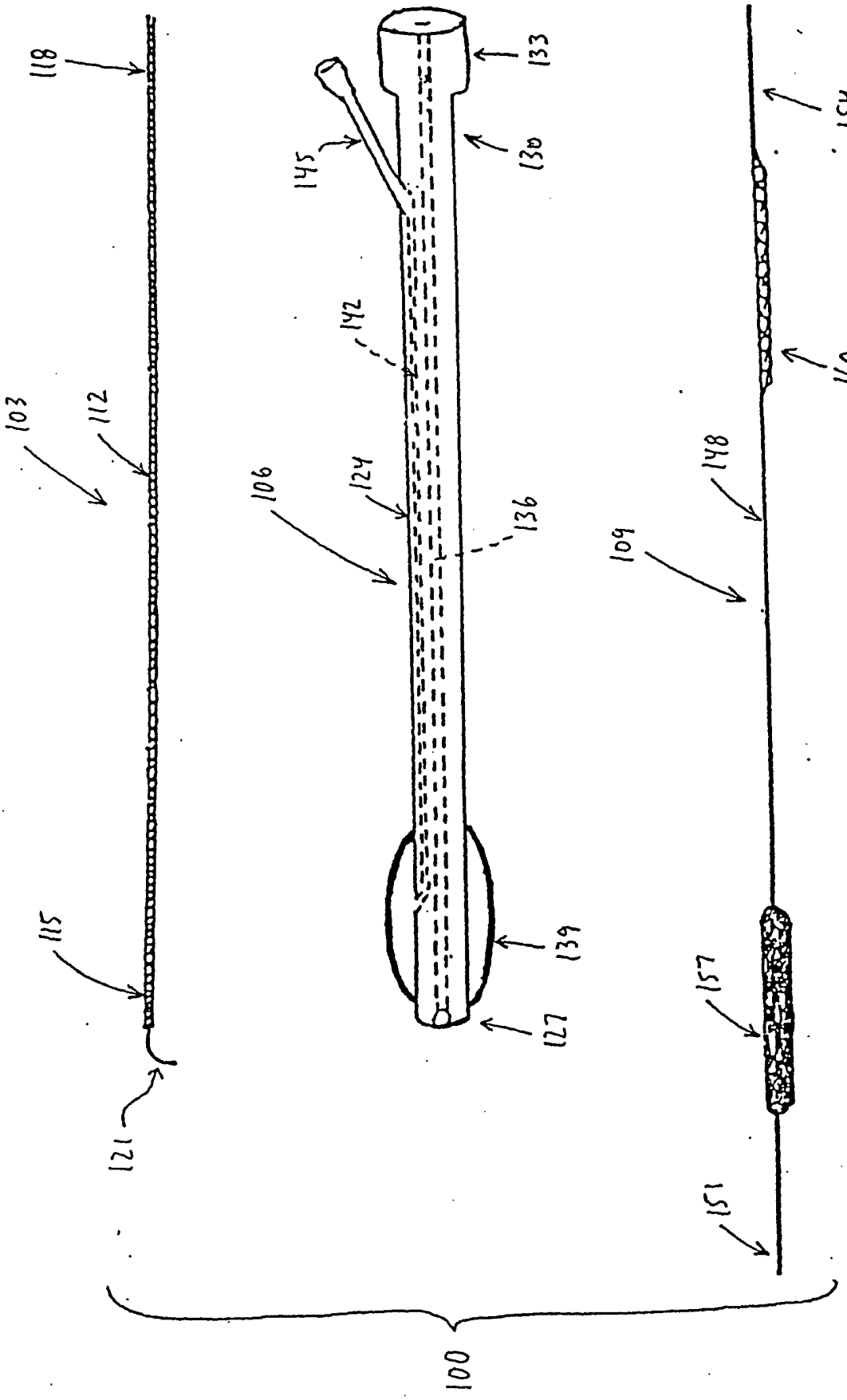
118
103
112
115
121
106
124
142
145
133
130
136
139
127
154
160
148
109
157
151
100

FIG. 3

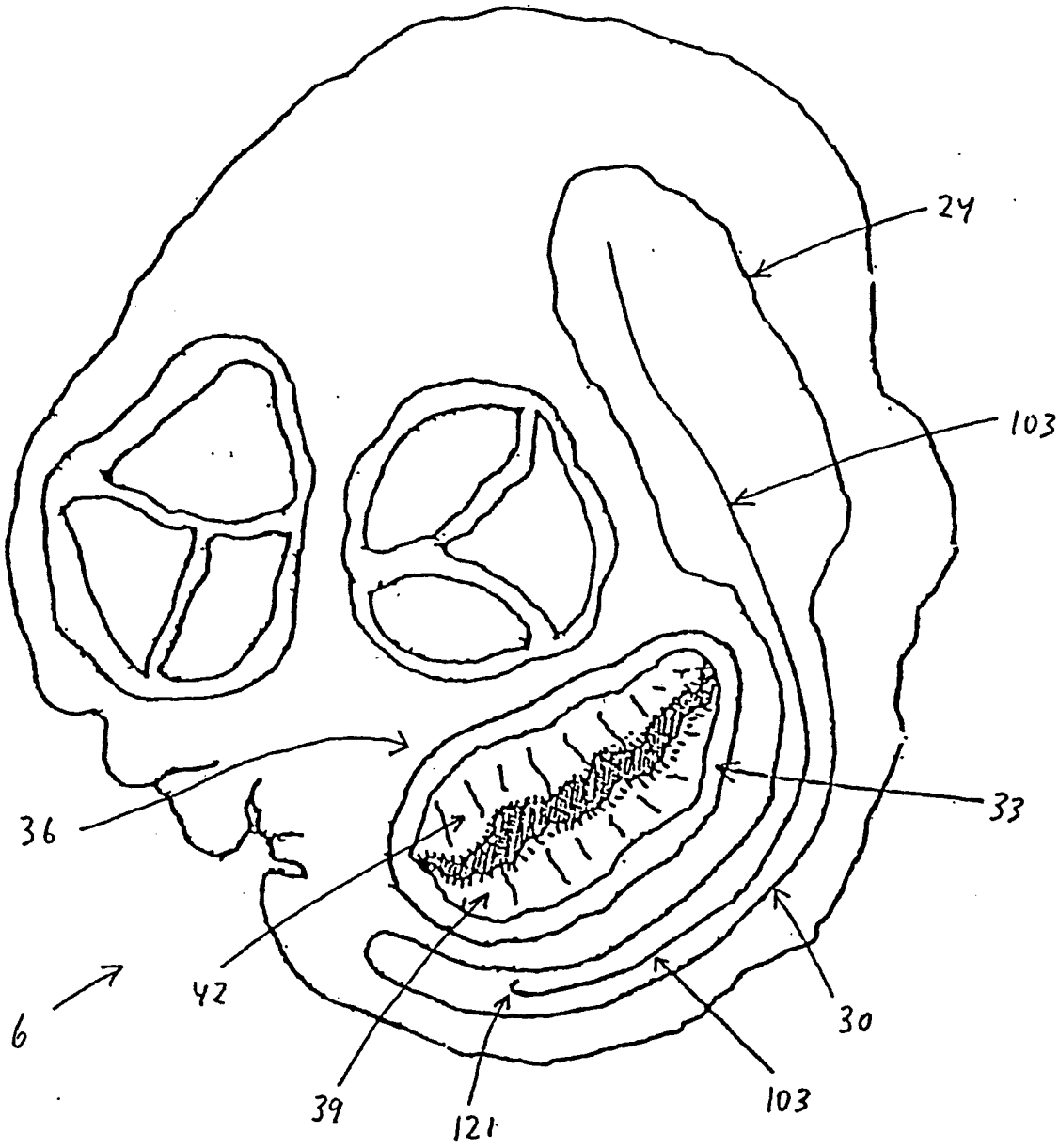

FIG. 4

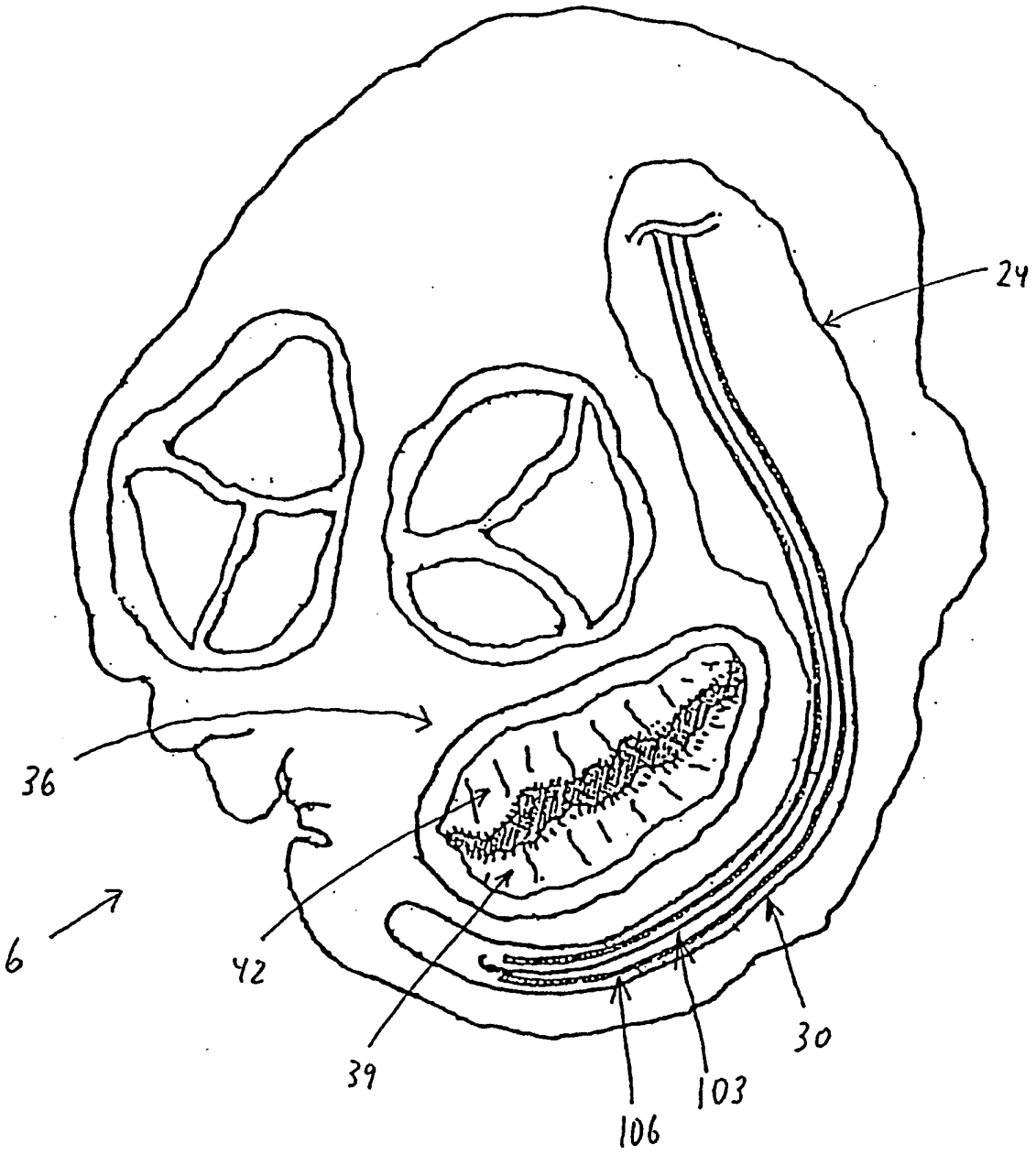

FIG. 5

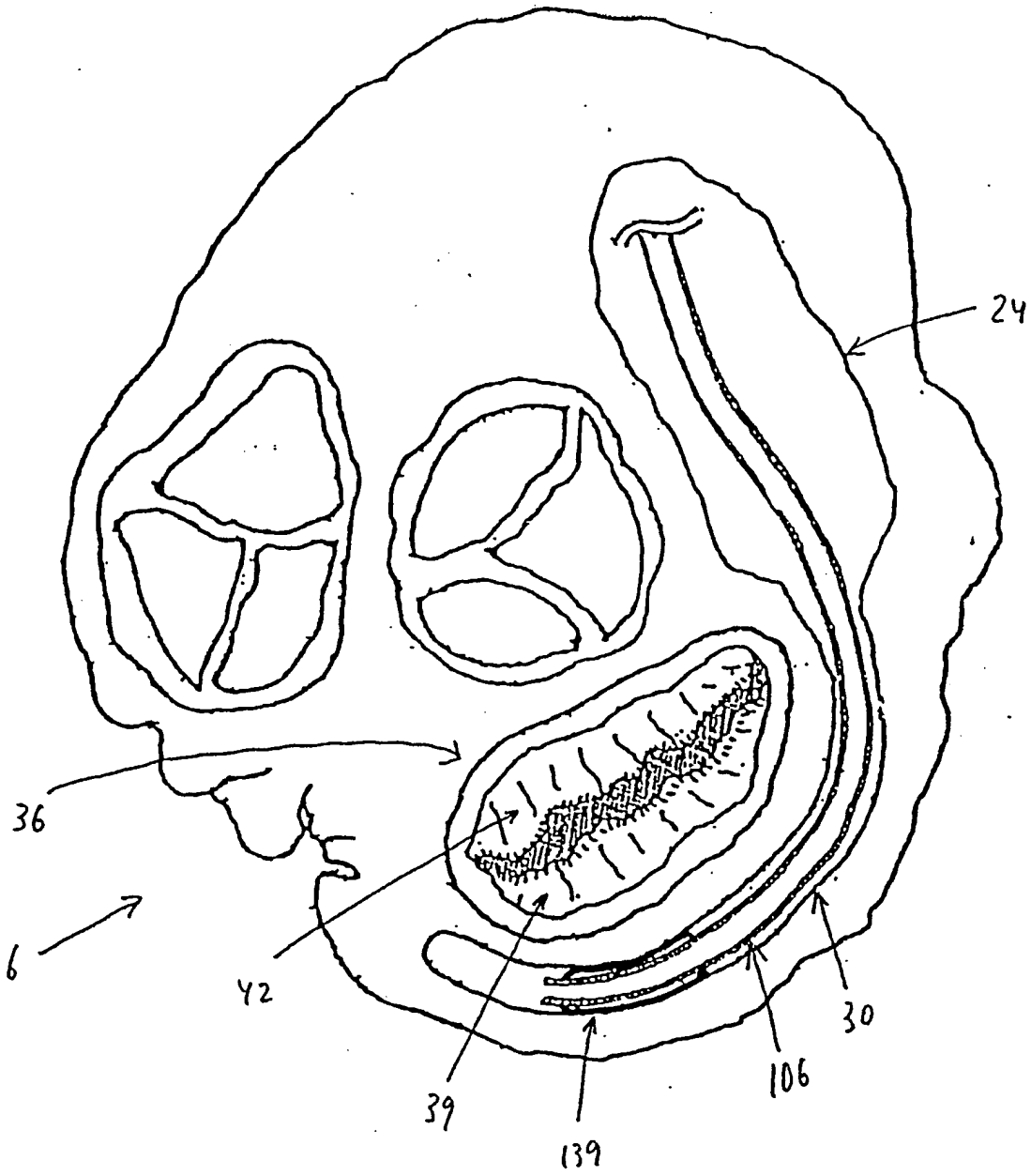

FIG. 6

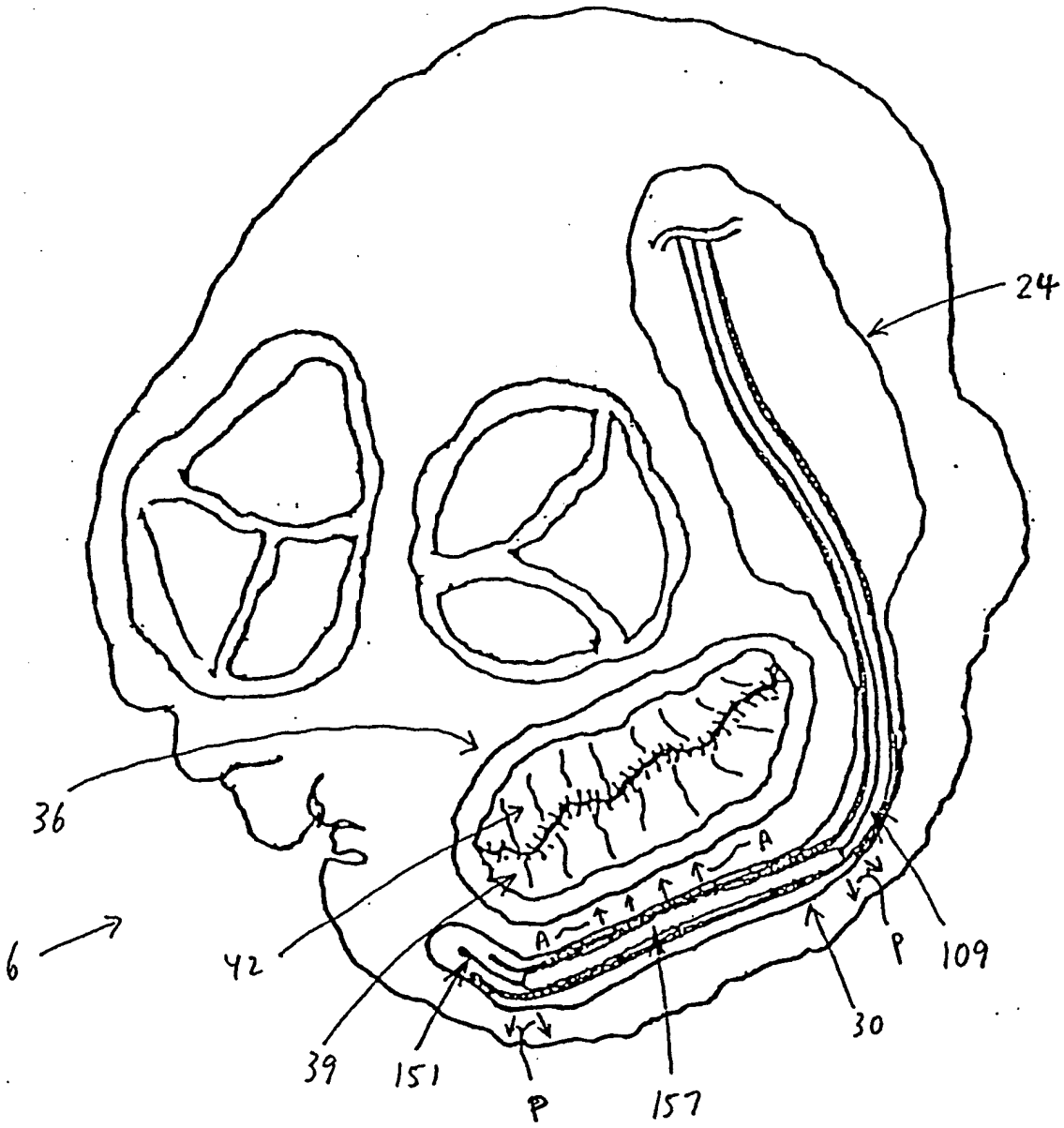

FIG. 7

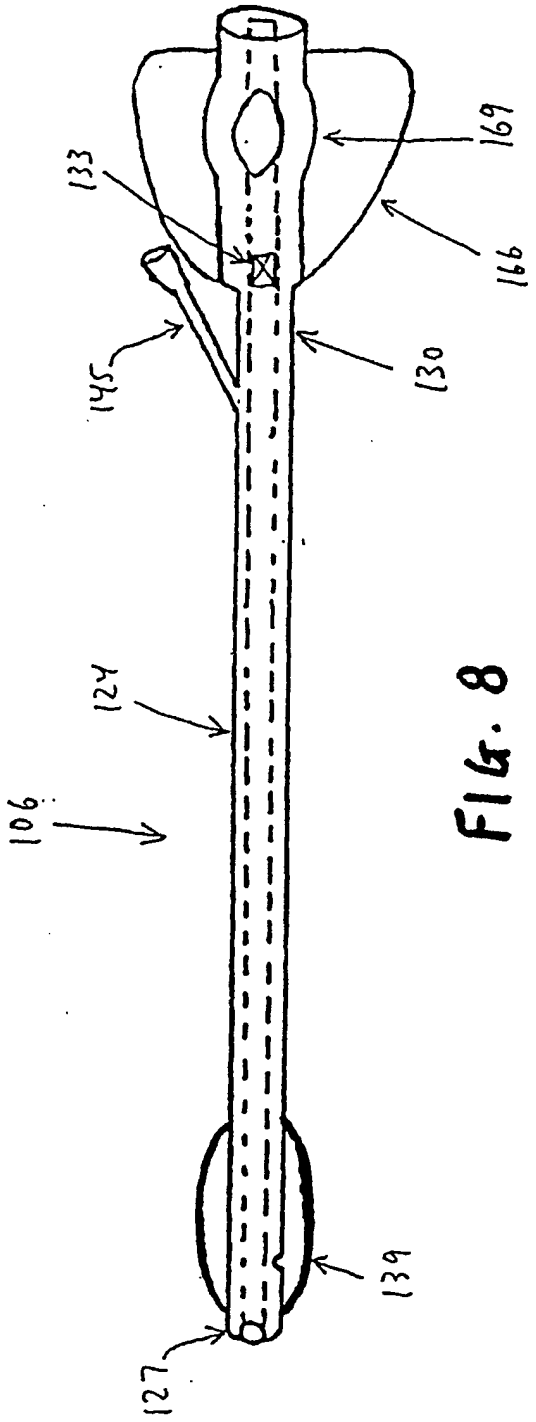

FIG. 8

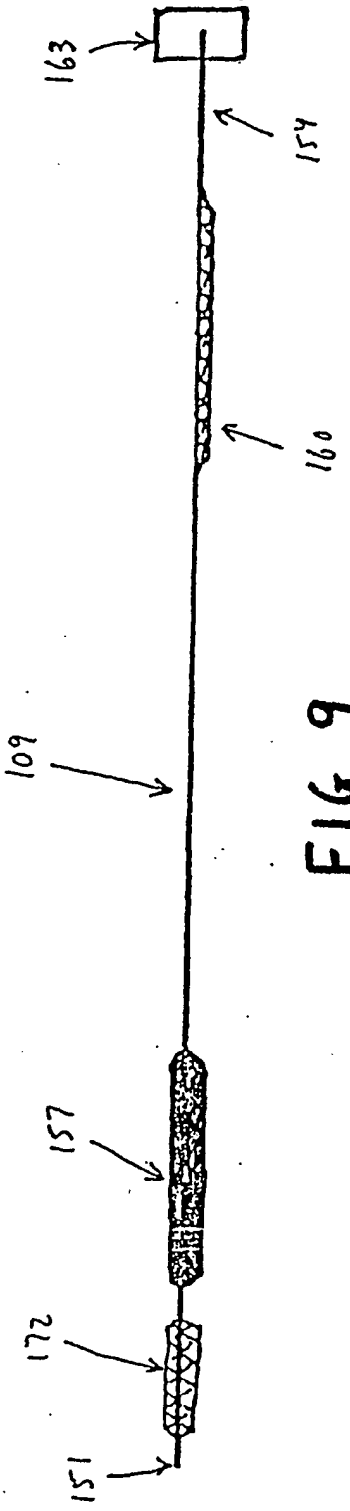

FIG. 9

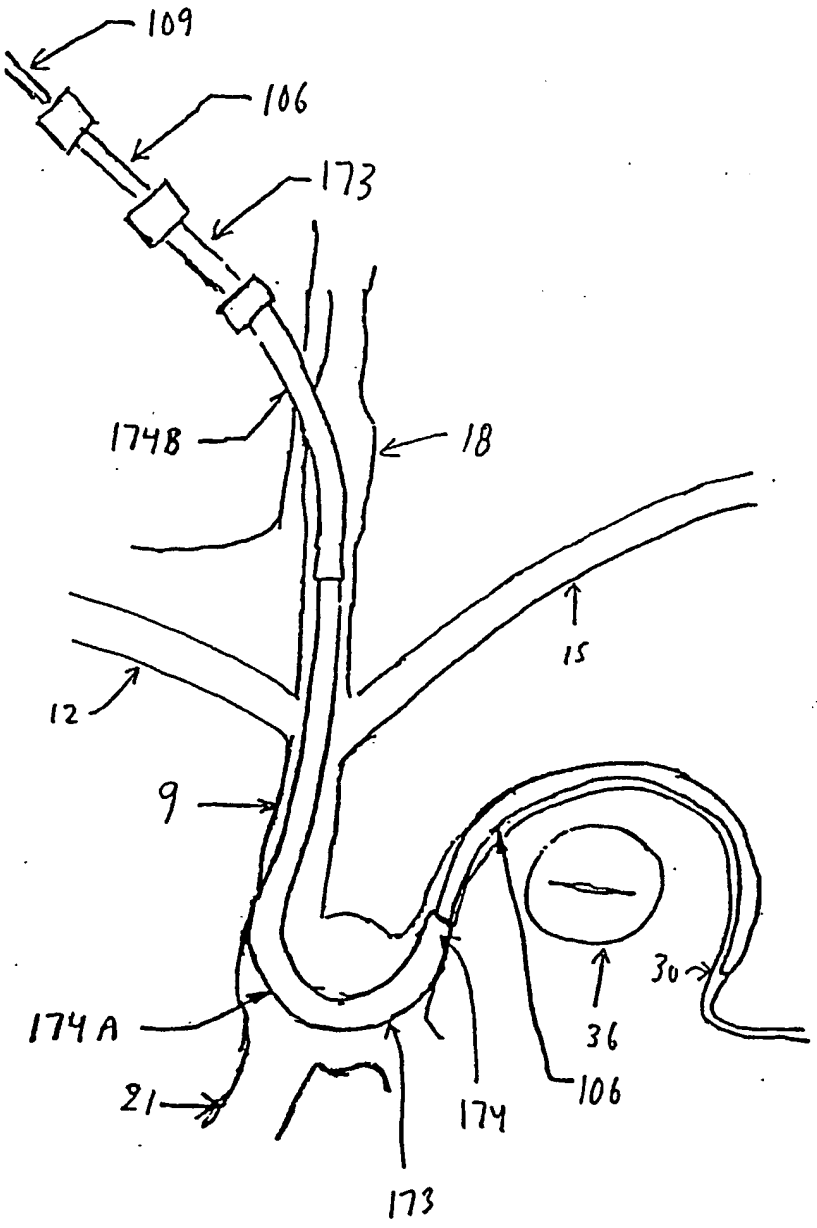

FIG. 9A

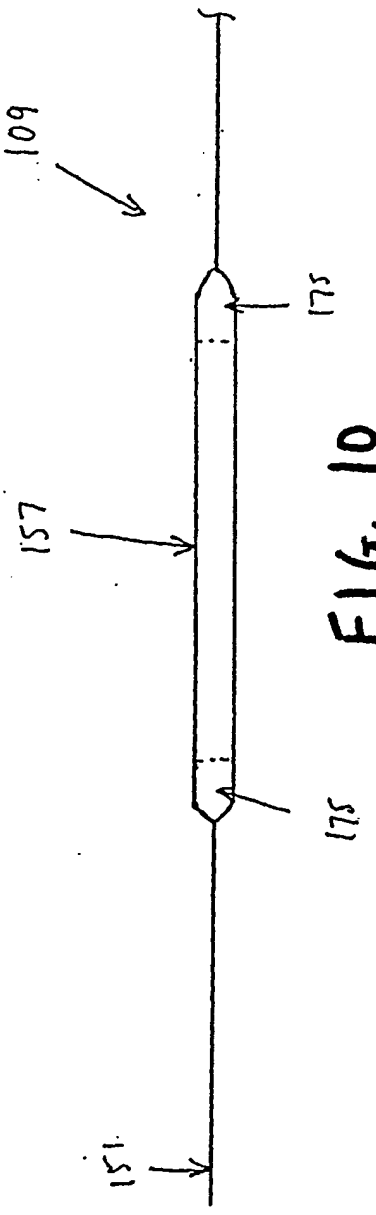

FIG. 10

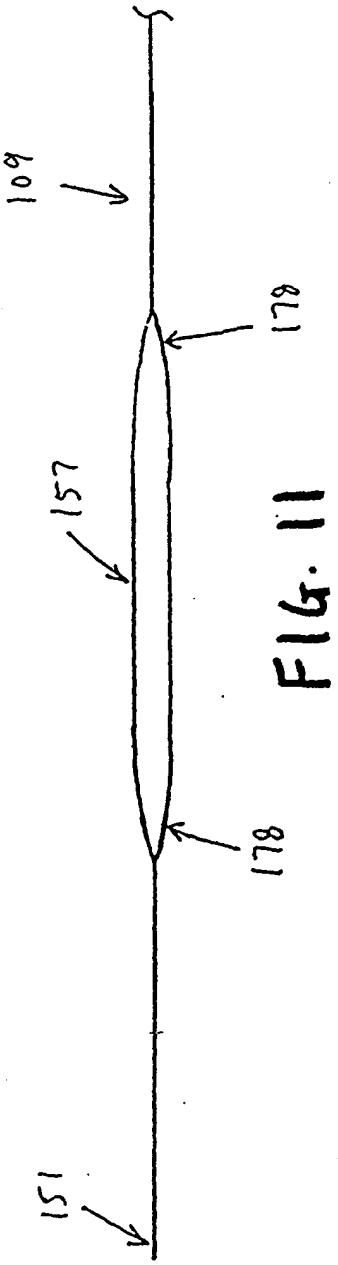

FIG. 11

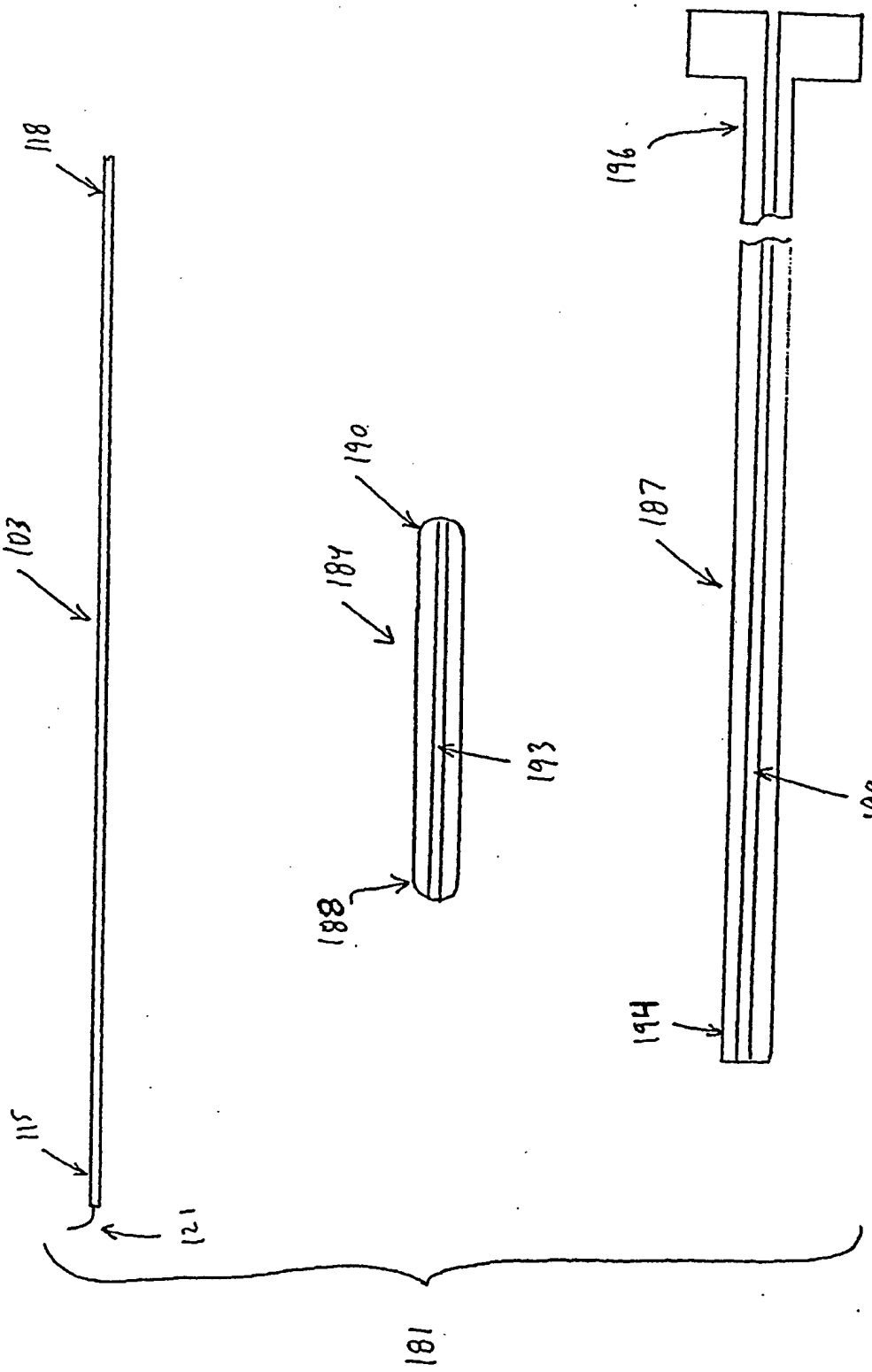

FIG. 12

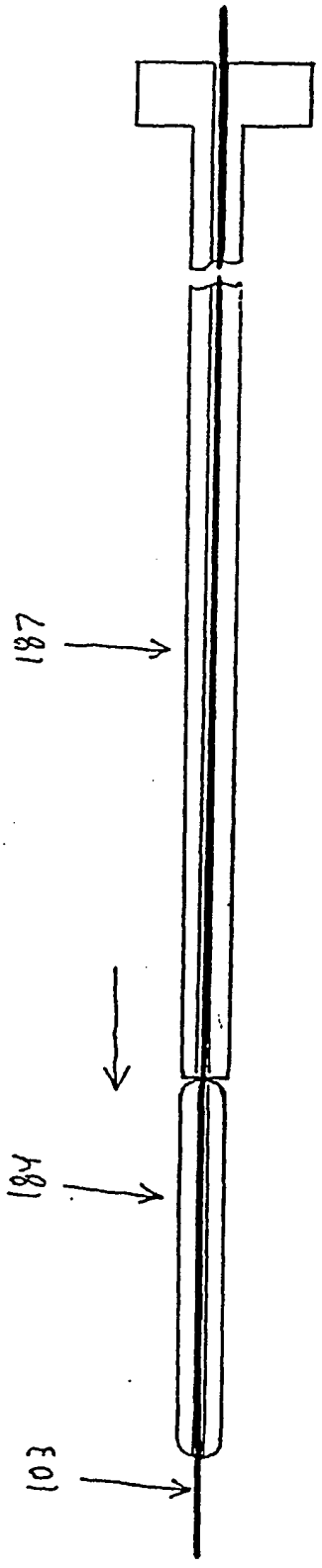

FIG. 13

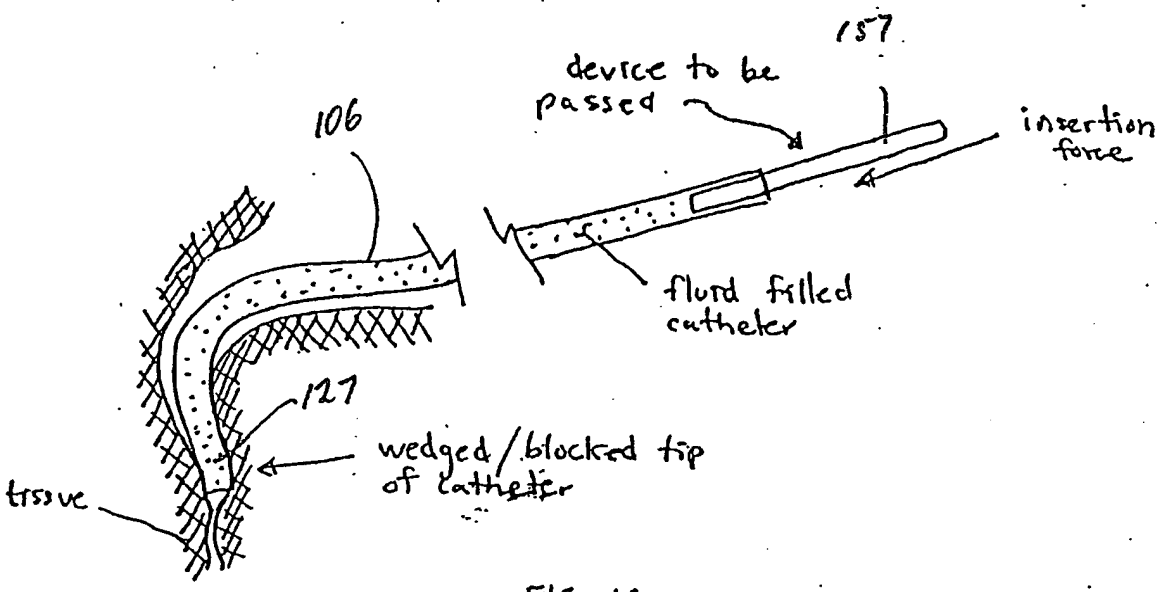
157
device to be passed
106
insertion force
fluid filled catheter
127
wedged/blocked tip of catheter
tissue

FIG. 14

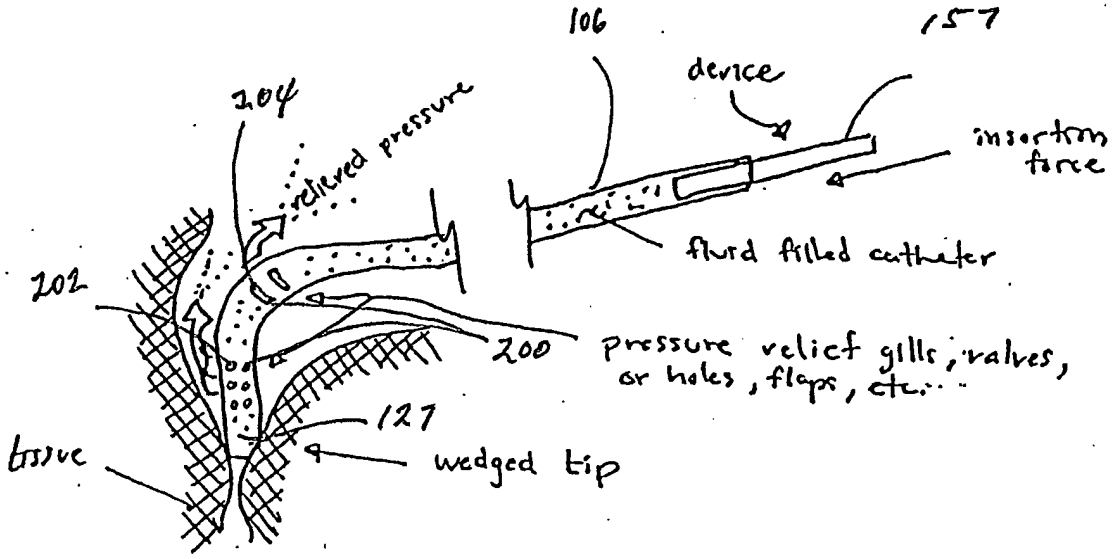
106
157
device
insertion force
fluid filled catheter
204
relieved pressure
202
200
pressure relief gills, valves, or holes, flaps, etc...
127
wedged tip
tissue

FIG. 15

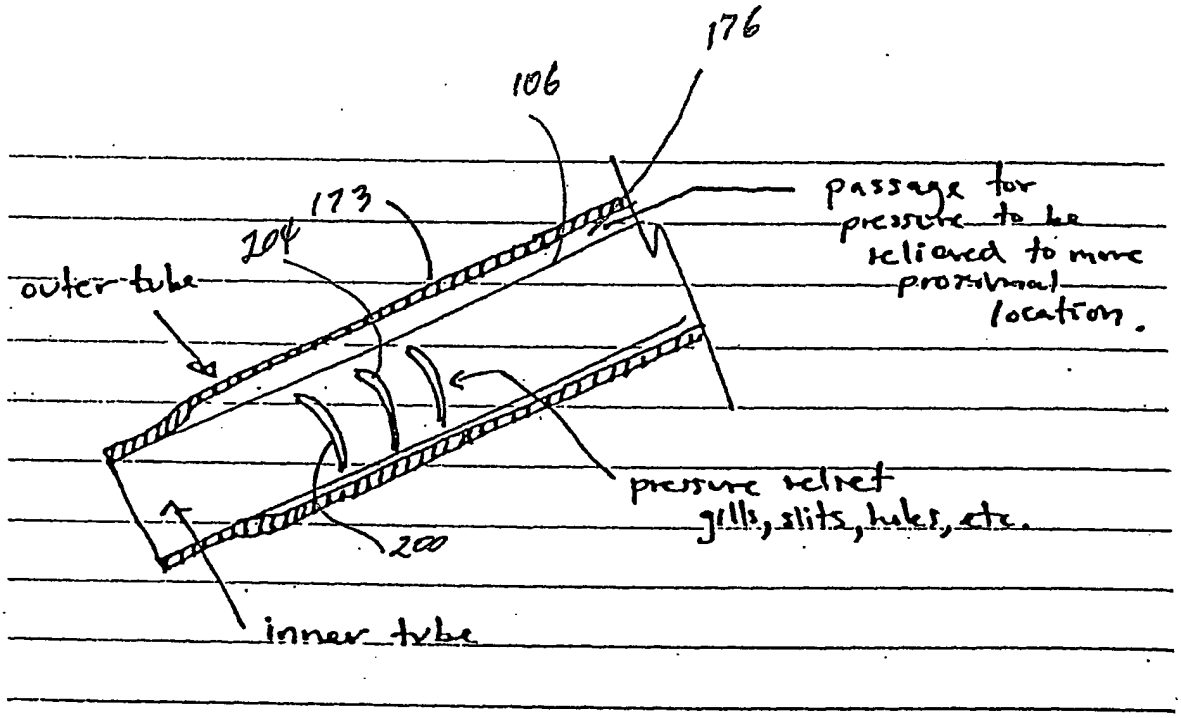
176
106
173
204
outer tube
passage for pressure to be relieved to more proximal location.
pressure relief grills, slits, holes, etc.
200
inner tube

FIG. 16

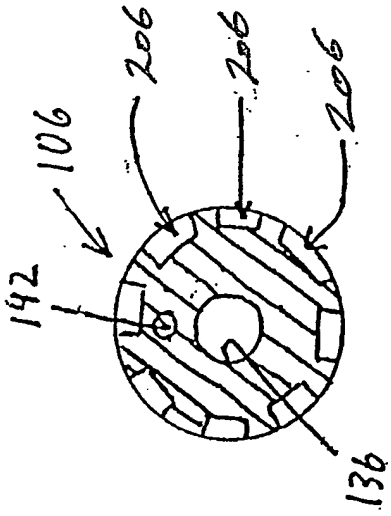

FIG. 18

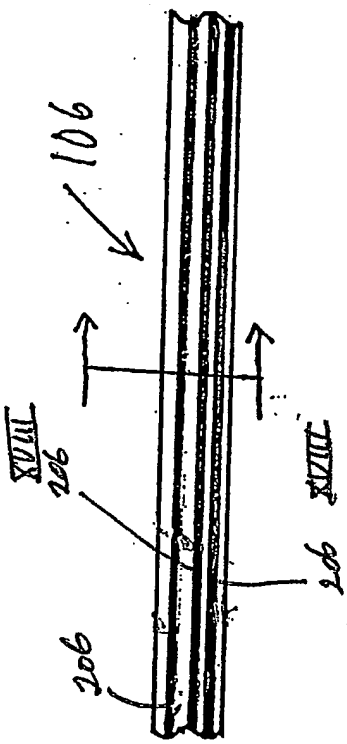

FIG. 17

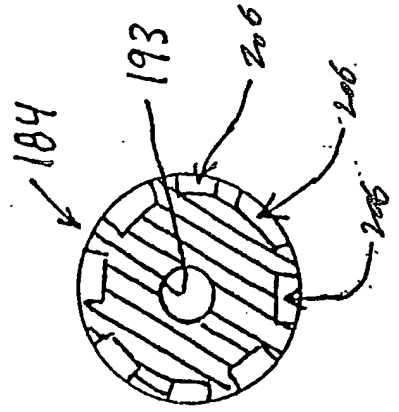

FIG. 2D

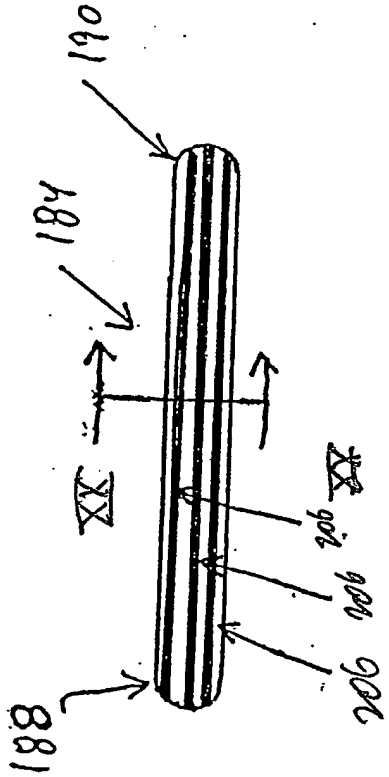

FIG. 19

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International Bureau

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(30) Priority Data:
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10/446,470 27 May 2003 (27.05.2003) US

(71) Applicant: VIACOR, INC. [US/US]; 260-B Fordham Road, Wilmington, MA 01887 (US).

(72) Inventors: COHN, William, E.; 104 Lagrange Street, Chestnut Hill, MA 02467 (US). LIDDICOAT, John, R.; 68 Myrtle Street, Apt. 4, Boston, MA 02114 (US). WOOLFSON, Steven, B.; Constitution Marina, 28 Constitution Road, P.O. Box 51837, Boston, MA 02205 (US). STREETER, Richard, B.; 66 Brookside Avenue, Winchester, MA 01890 (US).

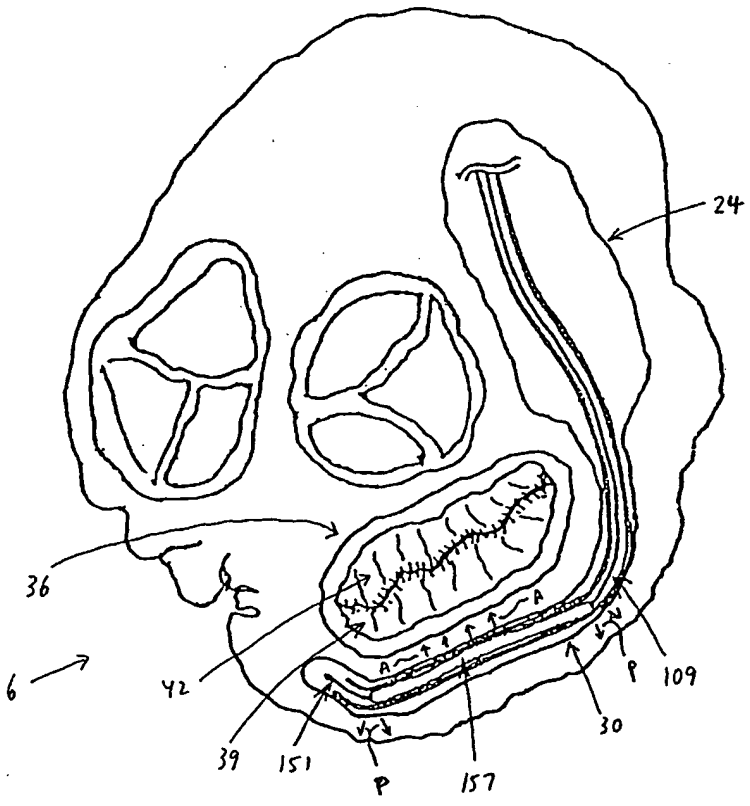
(74) Agent: PANDISCIO, Mark, J.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,

[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR IMPROVING MITRAL VALVE FUNCTION



(57) Abstract: A method and apparatus for reducing mitral regurgitation. The apparatus (157) is inserted into the coronary sinus (30) of a patient in the vicinity of the posterior leaflet (39) of the mitral valve, the apparatus being configured to straighten the natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve (36), whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation and reduce mitral regurgitation.

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ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/20284

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61F 2/24
US CL : 623/2.36
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/2.11,2.36, 904;606/108,191

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,210,432 B1 (Solem et al) 03 April 2001, Figs. 10,11, col. 2, lines 9-19,36-42, col. 4, lines 47-50.	1-12
X	US 6,119,037 A (Kellogg et al) 12 September 2000, Figs. 2,4, col. 4, lines 22,23,49-58.	13,14,18,19
X	US 5,476,506 A (Lunn) 19 December 1995, Figs. 1,2,5D, col. 2, lines 16-20,30,31, col. 4, lines 63-67.	20,21
X	US 5,569,201 A (Burns) 29 October 1996, Figs. 10,12, col. 3, lines 15-30, col. 4, line 34.	13-17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search
19 March 2004 (19.03.2004)

Date of mailing of the international search report
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Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Authorized officer
Brian Pellegrino

Telephone No. 703-308-0858

INTERNATIONAL SEARCH REPORT

PCT/US03/20284

Continuation of B. FIELDS SEARCHED Item 3:
EAST text terms:
coronary sinus, mitral valve, posterior leaflet, expandable body, stent, move

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/20284

Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

NEW ABSTRACT

A method and apparatus for reducing mitral regurgitation. The apparatus (157) is inserted coronary sinus (30) of a patient in the vicinity of the posterior leaflet (39) of the mitral valve, the apparatus being configured to straighten the natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve (36), whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation and reduce mitral regurgitation.

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(22) International Filing Date:
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(25) Filing Language: English

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(30) Priority Data:
60/425,877 13 November 2002 (13.11.2002) US

(71) Applicant: **VIACOR, INC.** [US/US]; 260-B Fordham Road, Wilmington, MA 01887 (US).

(72) Inventors: **COHN, William, E.**; 104 Lagrange Street, Chestnut Hill, MA 02467 (US). **LAMBRECHT, Gregory, H.**; 220 Elliot Street, Natick, MA 01760 (US). **LIDDICOAT, John, R.**; 68 Myrtle Street, APt. 4, Boston, MA 02114 (US). **MOORE, Robert, Kevin**; 4 Rolling Lane, Natick, MA 01760 (US). **STREETER, Richard, B.**; 66 Brookside Avenue, Winchester, MA 01890 (US). **DAVENPORT, Todd, F.**; 48 Salem Street, Andover, MA 01810 (US).

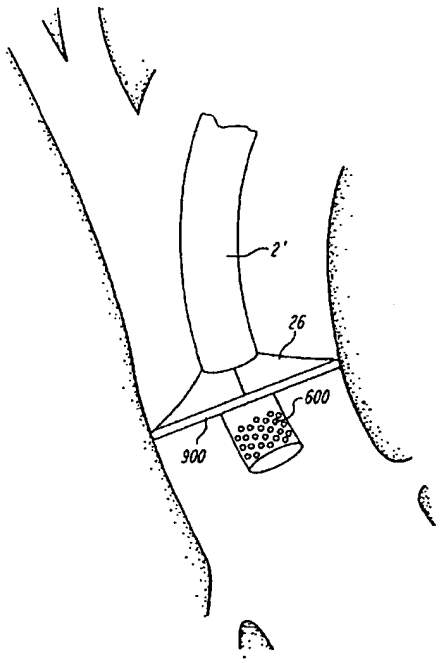
(74) Agents: **PANDISCIO, Mark, J.** et al.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: CARDIAC VALVE PROCEDURE METHODS AND DEVICES



(57) Abstract: Devices and methods for performing intravascular procedures without cardiac bypass include embodiments of temporary filter devices, temporary valves, and prosthetic valves. The temporary filter devices have a cannula (1) which provides access for surgical tools for effecting repair of cardiac valves. The cannula may have filters (71) which prevent embolitic material from entering the coronary arteries and aorta. The valve devices (26) may also have a cannula (2) for insertion of the valve into the aorta. The valve devices (26) expand in the aorta to occupy the entire flow path of the vessel and operate to prevent blood flow and to permit flow through the valve. The prosthetic valves include valve fixation devices (90) which secure the prosthetic valve to the wall of the vessel.

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European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/36639

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 29/00

US CL : 606/200, 159, 192

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/200, 159, 192, 193

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,168,579 B1 (TSUGITA) 02 January 2001 (19.01.2001), col. 9, lines 19-28, Fig. 5)	1-10 --- 11
X --- Y	US 6,258,120B1 (MCKENZIE et al.) 10 July 2001 (10.07.2001), see col. 13, lines 6-16, Fig. 24).	1-10 --- 11

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01 December 2004 (01.12.2004)

Date of mailing of the international search report

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Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

For Anhtuan T. Nguyen

Telephone No. 703-308-0858

Sheila H. Verley
Paralegal Specialist
Tech. Center 3700

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